

REMARKS

Claims 2 and 4-25 are pending in the present application. Claims 2, 4-13 and 19-25 are rejected.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

Claims 1-8, 10, 11 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Christian (U.S. Patent No. 4,708,931) in view of Schembri (U.S. Patent Publication No. 2004/0087033), the Applicant's admitted prior art (APA) and either Wilding (U.S. Patent Application Publication No. 2006/0223166), Anderson (U.S. Patent Application Publication No. 2005/0202504) or Childers (U.S. Patent Application Publication No. 2004/0086872).¹

It is the position of the Office Action that Christian discloses the invention as claimed, with the exception of the biopolymers and biopolymer solutions being transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner, and the teaching of the substrate being formed using an elastic material. The Office Action relies on Schembri to teach the elastic substrate, and relies on either the APA, Wilding, Anderson or Childers to teach the sequential transferring.

¹ The listing of claims in this rejection is incorrect. Instead of claims 1-8, 10, 11 and 13, claims 2 and 4-13 are addressed.

In Applicants' previously filing, it was submitted that the proposed modification would be unsatisfactory for its intended purpose, since waste or sample solution would leak out of the opening 126. In response, the Office Action states that “[t]here doesn't seem to be any support for this assertion in the Applicant's remarks. Wilding and Anderson each teach that it is known in the art to remove waste and/or sample solution from a detection area in a controlled manner. There appears to be no reason to believe that Christian's apparatus is particularly prone to leakage.” Thus, it appears that the Office Action is of the position that the combination of references would also include a waste reservoir attached to the opening 126 of Christian. It is noted that in Christian, samples and wash reagents are squeezed out through channel 122 and opening 126. Christian does not contemplate the inclusion of a waste reservoir of any kind. It is also noted that the proposed modification illustrated on page 13 of the March 7, 2007 does not includes a waster reservoir of any kind. Thus, Applicants respectfully submit that it would not have been obvious to further include a waste reservoir in the modification in order to alleviate the problem of leakage from the opening 126. Such inclusion of a waste reservoir would add to the bulk and cost of the device.

In the previously filing, Applicants further submitted that in the proposed modification, which is illustrated on page 13 of the March 7, 2007 Office Action, the sample solution would flow into microassay rod 10 and wash chambers 123 and 125. The Office Action concedes that based on his illustration, “it does seem like it would be possible for sample solution to be accidentally diverted into the wash chambers.” However, the Office Action states that each of the APA, Wilding and Anderson disclose a schematic in which sample solution flows directly

from a pre-processing area into a detection area without being redirected into a wash solution chamber. The Office Action thus concludes that one having ordinary skill in the art would recognize how to “redesign the apparatus of Christian to ensure that the sample is not needlessly moved into the wash chambers.”

In response, Applicants respectfully submit Office Action’s comments regarding the APA, Wilding and Anderson are misplaced. While these references do appear to disclose situations where sample solution flows directly from a pre-processing area into a detection area, the configuration in the APA, Wilding and Anderson appears to be significantly different from the proposed modification of Christian illustrated in the March 7, 2007 Office Action. Specifically, in the proposed modification, sample solution being moved from the inlet port to the microassay rod 10 would appear to reach a “fork in the road” where the wash chambers 123 and 125 and detection solution chamber 124 join the microassay rod 10. A similar configuration is not disclosed by any of the cited art. This configuration illustrates the problems associated with modifying a “parallel” system to being a hybrid of a “parallel” system and a “series” system. Without increasing the expense and complexity of the device by adding some type of one-way valves, contamination into chambers 123, 124 and 125 would necessarily result from the proposed modification. Applicants respectfully submit that this further illustrates that it would not have been obvious to modify Christian as proposed by the Office Action.

In Applicants’ previous filing, it was submitted that the proposed modification changes the principle of operation of Christian in several ways. Most importantly, Applicants noted that the combination of references changes the principle of operation from a “parallel” configuration

to a “series” configuration. More accurately, the proposed modification changes the principle of operation from a “parallel” configuration to a hybrid “parallel/series” configuration. In response, the Office Action states that:

It is agreed that the redesign of Christian would require changing the principle of operation from a biochip in which reagents are moved in “parallel” to one in which reagents are moved in “series.” However, this does not constitute a substantial reconstruction and redesign.

As explained in MPEP §2143.01, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Office Action’s statement appears to be based on a quotation from *In re Ratti*, stating that the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.”

However, Applicants respectfully submit that with respect to the proposed redesign, like in *Ratti*, once applicants had taught how this could be done, the redesign may, by hindsight, seem to be obvious to one having ordinary skill in the art. However, when viewed as of the time of applicants’ invention was made, and without the benefit of applicants’ disclosure, one having ordinary skill in the art would not have been prompted to modify the cited art in order to arrive at the claimed invention.

Additionally, it is impossible for a design change which modifies the principle of operation to be anything but substantial. The Office Action has conceded that the proposed modification changes the principle of operation of the closest cited art. Applicants respectfully reiterate that, as explained in MPEP §2143.01, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Thus, since the Office Action has conceded that the proposed combination of art results in a change in the principle of operation of the device, it cannot render the claims *prima facie* obvious. Favorable reconsideration is respectfully requested.

Claims 19-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Christian in view of Schembri, the Applicant's admitted prior art (APA) and either Wilding, Anderson or Childers, and in further view of McGarry (U.S. Patent No. 6,642,046).

It is the position of the Office Action that the combination of Christian, Schembri and either the APA, Wilding, Anderson or Childers teaches the invention as claimed, with the exception of teaching that a carrier is a glass slide. The Office Action relies on McGarry to provide this teaching.

The Office Action maintains the rejection from the previous Office Action, retaining the same reasoning. However, the Office Action did not respond to Applicants' previously filed remarks regarding claims 19-25. Applicants respectfully reiterate these remarks below.

McGarry is directed at a biochip having a substrate 22 which may be formed of a glass slide. A reaction chamber 30 is formed by an O-ring 48, a biochip (glass slide) 20 and a base plate 32. In response to the pending rejection, Applicants respectfully submit that it would not have been obvious to combine the teachings of McGarry with that of the other cited art. McGarry specifically discloses that reaction chambers are loaded using a pipet, then sealed. See column 12, lines 31-45.

On the other hand, as illustrated in Figures 20A-C of the present invention and discussed at page 18, line 26 to page 22, line 24, the invention of claim 19 includes the previously recited roller and a glass slide. Applicants respectfully submit that since McGarry discloses introduction of biopolymers using a pipet and subsequent sealing, it is incompatible with the teachings of claim 19, and all claims dependent thereon. Favorable reconsideration is respectfully requested.

Furthermore, as noted in at least MPEP 707.07(f), the Office Action is required to answer and address all traversals. This requirement is in addition to any repetition of a previously held position and is required to allow the applicant a chance to review the Office Action's position as to these arguments and to clarify the record for appeal.

“An examiner must provide clear explanations for all actions taken by the examiner during prosecution of an application.” MPEP 707.07(f) (The examiner should “take note of the applicant’s argument and answer the substance of it.”) However, the pending Office Action failed to address the substance of Applicants’ remarks provided in the August 30, 2007 Amendment.

Additionally and as further noted in MPEP 707.07(f), a failure of the Examiner to address the applicant's traversals can be deemed a failure to rebut these arguments so as to admit that the arguments have overcome the rejection. At the very least, the failure to address the applicant's traversals would render the Examiner's decision to again reject the claims arbitrary and capricious and invalid under the Administrative Procedures Act, 5 U.S.C. § 706, the standard under which such rejections are reviewed in view of Dickinson v. Zurko, 527 U.S. 150, 50 USPQ2d 1930 (1999).

As such, since the Office Action has not addressed the applicant's traversals with respect to claims 19-25 presented in the Request for Reconsideration of August 30, 2007, Applicants respectfully request that the Examiner withdraw the Final Office Action and issue a new Office Action or Notice of Allowance addressing the comments of the Amendment of August 30, 2007.

Allowable Subject Matter

Claims 14-18 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Office Action acknowledges that the cited prior art does not disclose the use of a biochip cartridge that includes a tabular substrate and flexible cover that are made separable into a first and second housing. However, Applicants respectfully decline rewriting claims 14-18 in independent form at this time.

Application No.: 10/716,417
Art Unit: 1744

Request for Reconsideration
Attorney Docket No.: 032106

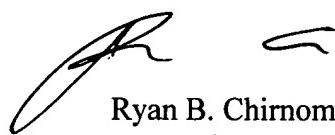
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

RBC/nrp